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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,458	11/28/2003	Leslie William Organ	BEW-005	9862
959 7590 09/05/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER TOWA, RENE T	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 09/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/724,458

Applicant(s)

ORGAN ET AL.

Examiner

Rene Towa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 16-24 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This Office action is responsive to an amendment filed June 11, 2007. Claims 1-2, 4-14 and 16-24 are pending. Claims 1, 4, 13, and 16 have been amended. Claims 3 and 15 have been cancelled. No new claim has been added.

### *Claim Objections*

2. The objections are withdrawn due to amendments.

### *Claim Rejections - 35 USC § 103*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. **Claims 1-2, 7-11, 13-14, 19-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ (US Patent No. 6,122,544) in view of Sun et al. (US Patent No. 6,391,024).

In regards to claims 1 and 13, Organ discloses a system for diagnosing the possibility of disease in a body part, the method comprising

- providing an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part;
- making an electrode assessment measurement with the electrode array;
- making a diagnosis measurement with the electrode array;
- obtaining an electrical property of the body part based on the diagnosis measurement; and
- diagnosing the possibility of disease based on the electrical property of the body part (see fig. 5; column 3/lines 29-44; columns 4-11, lines 14-46).

In regards to claims 2 and 14, Organ discloses a system wherein the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode pair that are applied to the body part (see column 4, lines 35-39).

In regards to claim 7, Organ teaches a system wherein the plurality of electrodes includes  $n_{cl}$  current injection electrode pairs, and  $n_{cl}$  associated voltage measurement electrode pairs, where  $n_{cl}$  is an integer greater than zero (see Column 4, lines 35-38).

In regards to claim 8, Organ discloses a system wherein the step of making a diagnosis measurement includes applying the  $n_{cl}$  current injection electrode pairs on the body part; and applying the  $n_{cl}$  voltage measurement electrode pairs on the body part (see Column 4, lines 35-59).

In regards to claims 9-11 and 19-23, Organ discloses a system wherein the step of making a diagnosis measurement further includes

injecting a first current between a first pair of the  $n_{cl}$  current injection electrode pairs;

measuring the resultant voltage difference  $V_{\text{sub.1.sup.M}}$  between the voltage measurement electrode pair associated with the first current injection electrode pair; and repeating the preceding two steps of injecting and measuring with the other electrode pairs until all  $n_{cl}$  voltage differences,  $\{V_1^M, V_2^M, \dots, V_{n_{cl}}^M\}$  are obtained; wherein the electrical property is impedance; wherein the step of obtaining includes using the  $n_{cl}$  voltage differences to obtain associated measured impedances,  $\{Z_1^M, Z_2^M, \dots, Z_{n_{cl}}^M\}$ , where  $Z_j^M$  is the measured impedance between the voltage electrodes associated with

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the jth current injection electrode pair (see Columns 6-8, lines 5-14; see columns 6-11, lines 5-53).

*Organ discloses a system, as described above, that fails to explicitly teach an electrode assessment measurement that includes a bipolar measurement.*

However, Sun et al. disclose a system comprising:

providing an electrode array 46 (see figs. 8a-c);

making a bipolar electrode measurement with the electrode array by utilizing one current injection electrode and one voltage measurement electrode (see col. 4, lines 6-25);

determining whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value (i.e. reference impedance) (see figs. 1 & 8a-c; column 3/lines 37-50; column 4/lines 6-56).

Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Since both Organ and Sun et al. teach systems for measuring tissue impedance via an array of electrodes, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Organ*

*with an electrode assessment module similar to that of Sun et al. in order to measure the adequacy of contact between an electrode and biological tissue (see Sun et al., column 3/lines 28-30).*

5. **Claims 12 and 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Sun et al. ('024) further in view of Dempsey et al (US Patent No. 5,419,337).

Organ as modified by Sun et al. discloses a system, as described above, that teaches all the limitations of the claims except Organ as modified by Sun et al. do not explicitly teach a system comprising a GUI.

However, Dempsey et al discloses a graphical user interface that includes the input of information by the user to select certain ECG strips for sampling by the computer (see Column 5, lines 13-29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Organ with a user interface, as taught by Dempsey et al, to select certain ECG strips for sampling by the computer.

6. **Claims 4-6 and 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Sun et al. ('024) further in view of Gallup et al. (US Patent No. 5,372,141).

Organ as modified by Sun et al. discloses a system, as described above, that teaches all the limitations of the claims except Organ as modified by Sun et al. do not teach measuring a phase. However, Gallup et al. discloses a system for determining

impedance comprising the steps of determining a phase (see column 7/lines 13-column 8/line 3).

Since Organ as modified by Sun et al. disclose a method wherein electrode assessment includes measurement of an impedance, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Organ as modified by Sun et al. with an impedance determining step similar to that of Gallup et al. since such a modification would amount to a design choice that would serve the same purpose of determining the impedance. Moreover, the Applicant has not disclosed that determining an impedance by way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem over the prior art.

7. **Claims 4-6 and 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Sun et al. ('024) further in view of Feldman (US Patent No. 5,788,643).

Organ as modified by Sun et al. discloses a system, as described above, that teaches all the limitations of the claims except Organ as modified by Sun et al. do not teach measuring a phase.

However, Feldman discloses a system for determining impedance comprising the steps of determining a phase (see figs. 1-2).

Since Organ as modified by Sun et al. disclose a method wherein electrode assessment includes measurement of an impedance, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a

system similar to that of Organ as modified by Sun et al. with an impedance determining step similar to that of Feldman since such a modification would amount to a design choice that would serve the same purpose of determining the impedance. Moreover, the Applicant has not disclosed that determining an impedance by way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem over the prior art.

### ***Response to Arguments***

8. Applicant's arguments filed June 11, 2007 have been fully considered but they are not persuasive. Applicant contends that Sun et al. fails to teach comparing the bipolar assessment measurement to a known value. This argument has been considered but has not been deemed persuasive.

It is noted that the Applicant's claim only calls for the "value" to be "known" at the time of the comparison. The term "known" is defined by *Webster's II New Riverside University Dictionary (1994)* to mean "proved, satisfactorily specified, or completely understood." As such, as admitted by Applicant (see pages 10-11 of Remarks dated June 11, 2007), Sun et al. disclose the step of making a bipolar reference impedance measurement, which reference impedance is later compared to a bipolar assessment impedance. As such, the Examiner submits that the reference impedance is "satisfactorily specified" and therefore "known" for comparison with the assessment impedance measurement such that Sun et al. determines whether the plurality of electrodes are suitably coupled to the body part based on a comparison of a bipolar electrode assessment measurement to a known value (i.e. reference impedance). In



response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., determining that the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a bipolar electrode assessment measurement associated with population, demographic or anthropometric data) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In view of the foregoing, the rejections in view of Sun et al. are maintained.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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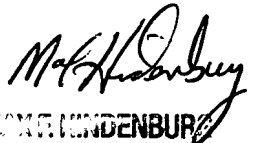
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758.

The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information in regards to the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/

  
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PATENT EXAMINER  
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